> because the specification, while being enabling for some types of cancer, does not reasonably provide enablement for 'treating cancer' in general. The specification does not enable any person of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. ... The Skilled Artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic agent (pages 2-3 of the Office Action).[1]

Applicants' previous arguments related to the fact that the method of independent claim 1 includes **contacting the cells with an effective amount of a compound** and **determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions** and one of ordinary skill in the art reading the specification would understand how to contact cells with an effective amount of a compound, and determine whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions. In response, the Examiner states at page 4 of the Office Action that

> independent claim 1 recites "a method of inhibiting histone deacetylase [...] activity in cells, thereby treating one or more disorders [...]." In the specification Cancer is named as one of the disorders to be treated via the applicant's method. The treatment of all types of cancer (as understood by the generic word cancer) is [sic] not enabled by the specification. Also note that the applicant has elected cancer as the disorder to be treated.

The method of claim 1 requires at least two actions to occur:

(1) contacting the cells with an effective amount of a compound, and

(2) determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions.

Specifically, claim 1 recites "contacting the cells with an effective amount of a compound ... thereby treating one or more disorders mediated by histone deacetylase." Contrary to the reading imposed by the Examiner, the clause in claim 1 "merely states the result of the limitations in the claim" and, as a result, "adds nothing to the patentability or substance of the claim."[2] In other words, by "contacting the cells with an effective amount of a compound" the

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[1] *In re Bunting*, 163 USPQ 689 (1969) is cited to support the lack of enablement rejection. However, *In re Bunting* relates only to assessing the utility of a claimed invention. Thus, *In re Bunting* is inapposite to the maintained rejection.

[2] *Texas Instruments Inc. v. United States Inter'l Trade Comm'n.*, 988 F.2d 1165, 1172 (Fed. Cir. 1993).

method "treat[s] one or more disorders mediated by histone deacetylase." The act of "contacting" then allows one to "determin[e] whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions." Thus, the "treatment" described in the claim is "result" of contacting cells with an effective amount of a compound of claim 1. The fact that a disorder is treated, and the identity of the disorder, is not the invention being claimed.

Indeed, the fact that Applicants elected cancer as the disorder being treated does not limit the scope of claim 1. The Examiner required election of a species for examination in the action mailed November 6, 2001. Such an election does not alter the scope of the claim presented for examination. See MPEP 806.02.

Finally, the Examiner's statement that "treatment of all types of cancer ... is [sic] not enabled by the specification" disregards the words of the claim. As discussed above, the "treatment" is a "result" of contacting cells with an effective amount of a compound of claim 1. The Examiner does not contend that contacting the cells with an effective amount of a compound, and determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions are not enabled by the specification. This is because these steps are clearly enabled by the specification.[3]

Accordingly, Applicants respectfully request reconsideration and withdrawal of the lack of enablement rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 2, 4-7, 10, 12, 17-18 and 40-46 have been rejected as under 35 U.S.C. § 103(a) as being unpatentable over Richon *et al.*, *Proc. Nat. Acad. Sci.* 95(6):3003-7 (1999) ("Richon") and Marks *et al. J. Nat. Cancer Inst.* 92(5):1210-6 (2000) ("Marks"). See pages 5-6 of the Office Action. As stated in the Office Action,

> Marks et al. teaches that hydroxamic acid-based HPCs are potentially effective agents for cancer therapy, see abstract (reference FF of IDS).
>
> Richon et al. and Marks et al. do not explicitly teach the elected compound in their method of treating cancer.

[3] Applicants do not concede that the specification does not enable treatment of cancer in cells, but as that is not what is claimed, this rejection should be withdrawn.

> It would have been obvious to one of ordinary skill in the art at the time the invention was to employ the elected compound in a method of treating cancer.
>
> One of ordinary skill in the art would have been motivated to employ the elected compound in a method of treating cancer because the elected compound is a hydroxamic acid derivative. The Skilled Artisan would reasonably expect the elected compound, a derivative of hydroxamic acid to exhibit therapeutic effects similar to hydoxamic [sic] acid because structurally related compounds would have been expected to have similar therapeutic effects (pages 3-4 of the Office Action).

As argued previously, neither Richon nor Marks, nor their combination, describe or suggest a method of inhibiting histone deacetylase activity in cells that includes **contacting the cells with an effective amount of a compound of formula (I)** and **determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions**. Richon describes the compounds suberoylanilide hydroxamic acid (SAHA) and m-carboxycinnamic acid bishydroxamide (CBHA). These compounds are not compounds included in claim 1. Marks also describes histone deacetylase inhibitors, but none of the compounds disclosed therein (see Figure 3) are compound included in claim 1. Indeed, contrary to the assertion made in the Office Action, Richon does not suggest any modifications of SAHA or CBHA, and Marks does not suggest any modifications of the compounds disclosed in Figure 3. Neither Marks nor Richon provide any motivation to modify the compounds disclosed in the references. Thus, Marks and Richon, taken together or separately, do not teach or suggest the method of independent claim 1. Claim 1, and claims that depend from claim 1 are patentable over Marks and Richon.

In response, the Examiner states that "both references indicate that the anti-cancer activity as well as the HDAC inhibitory activity of hydroxamic acid compounds are known." See page 4 of the Office Action. This statement does address Applicants' position that Richon does not suggest any modifications of SAHA or CBHA, and Marks does not suggest any modifications of the compounds disclosed in Figure 3 or Figure 4. Neither Marks nor Richon provide any motivation to modify the compounds disclosed in the references.

The Examiner also states that "Marks et al. provides a guide in choosing hydroxamic acid derivatives ... that have "a polar site, the hydroxamic acid group, a six-carbon hydrophobic

methylene spacer, a second polar site and a terminal hydrophobic group." See page 5 of the Office Action. However, contrary to the assertion of the Examiner, Marks does not suggest any modifications of the compounds disclosed in Figure 3 or Figure 4 of Marks. Specifically, the groups recited in independent claim 1, specifically the particular groups of A, Y^1, L, Y^2, X^1 and X^2 are not described or suggested by Marks. The generalized features quoted from Marks by the Examiner do not describe or suggest the particular groups of the compounds of claim 1. The compounds of claim 1 are not structurally related to either SAHA or CBHA. Chemically, both SAHA (N-phenyl-N'-hydroxy-bisamide) and CBHA (N,N'-dihydroxy-bisamide) are the "derivatives" of bis-amide. Indeed, Marks does not describe or suggest **contacting the cells with an effective amount of a compound of formula (I)** and **determining whether the level of acetylated histones in the treated cells is higher than in untreated cells under the same conditions**.

Thus, claim 1 and claims that depend therefrom are patentable over Marks or Richon. Applicants respectfully request reconsideration and withdrawal of this rejection.

Attached is a marked-up version of the changes being made by the current amendment.

CONCLUSIONS

Applicant asks that all claims be allowed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 7.23-02

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Version with markings to show changes made

In the claims:

Claims 54-66 have been cancelled.